July 29, 2016

Comments on the Proposed Healthy Ohio Program 1115 Demonstration Waiver

On behalf of Equitas Health, and the Ohio AIDS Coalition and the citizens of Ohio affected by HIV and AIDS, we are writing to comment in opposition to the proposed Healthy Ohio Waiver. Equitas Health, formerly AIDS Resource Center Ohio, is one of the nation's premier providers of a comprehensive, holistic, and coordinated response to HIV, from prevention to diagnosis and treatment. The Ohio AIDS Coalition (OAC) is a division of Equitas Health. The Coalition provides education and advocacy, appearing as a voice for Ohioans with HIV.

Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve demonstration projects that promote the objectives of the Medicaid and CHIP programs. There are general criteria CMS uses to determine whether Medicaid/CHIP program objectives are met. These criteria include whether the demonstration will:

1. increase and strengthen overall coverage of low-income individuals in the state;
2. increase access to, stabilize, and strengthen providers and provider networks available to serve Medicaid and low-income populations in the state;
3. improve health outcomes for Medicaid and other low-income populations in the state; or
4. increase the efficiency and quality of care for Medicaid and other low-income populations through initiatives to transform service delivery networks.

Each of those standards is violated by the proposed Waiver. The source of those violations are the statutes, Ohio Revised Code 5166.40 et seq. http://codes.ohio.gov/orc/5166 requiring certain terms of the Waiver. In particular, the waiver is in violation of or contrary to multiple provisions in federal law and place Ohioans with HIV in a tenuous position. Some of the defects caused by the underlying statutes are the following:

- A violation of MOE under Section 1902(a)(74) of the Social Security Act,
- A violation of Section 1903(c) of the Social Security Act,
- A violation of rights granted under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 and the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009),
- A violation of Section 1557 of the Patient Protection and Affordable Care Act,
- Placing charitable organizations and health care providers at risk of civil or criminal penalties,
- Not complying with the requirements of 26 USC 223., and
- Unlawfully interfering with a mandatory entitlement under federal law.

The following pages provide further explanation of each of the incurable defects in the underlying statutes.

I. THE WAIVER CANNOT BE APPROVED BECAUSE IT VIOLATES MOE REQUIREMENTS ENACTED AS PART OF THE ACA AND MOE IS EXPRESSLY NOT SUBJECT TO WAIVER UNDER THE SOCIAL SECURITY ACT.

42 U.S.C. 1396a(a)(74) requires states participating in the Medicaid program to "provide for maintenance of effort under the State plan or under any waiver of the plan in accordance with subsection (gg);" (Underscore added.)

Section gg states the following:

> **(gg) Maintenance of effort**
> **(1) General requirement to maintain eligibility standards until State exchange is fully operational**
> Subject to the succeeding paragraphs of this subsection, during the period that begins on March 23, 2010, and ends on the date on which the Secretary determines that an Exchange established by the State under section 18031 of this title is fully operational, as a condition for receiving any Federal payments under section 1396b (a) of this title for calendar quarters occurring during such period, a State shall not have in effect eligibility standards, methodologies, or procedures under the State plan under this subchapter or under any waiver of such plan that is in effect during that period, that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under the plan or waiver that are in effect on March 23, 2010.
> **(2) Continuation of eligibility standards for children until October 1, 2019**
> The requirement under paragraph (1) shall continue to apply to a State through September 30, 2019, with respect to the eligibility standards, methodologies, and procedures under the State plan under this subchapter or under any waiver of such plan that are applicable to determining the eligibility for medical assistance of any child who is under 19 years of age (or such higher age as the State may have elected).
>
> (Underscore added)

The proposed Waiver applies to 18 year olds. Any substantive, operational, or administrative requirement that imposes a new health savings account on any person who is 18 is a new eligibility standard, methodology, and procedure. Eligibility standards cannot be changed until October 1, 2019 at the earliest. The MOE restrictions are the same as those established under the American Recovery and Reinvestment Act and it applies to eligibility standards, methodologies, and procedures, and cannot be more restrictive than those in effect on March 23, 2010.

Section 2.6 on page 17 of the Waiver lists a series of changes to eligibility standards, methodologies, and procedures. Additionally, Section 4.5 on page 25 of the Waiver sets out new copayment and deductible obligations. For any individual who is age 18, ALL of those changes listed in sections 2.6 and 4.5 are categorically prohibited by Section 1902(A)(74) of the Social Security Act. For that reason, the waiver cannot be approved by CMS.

II. THE WAIVER CANNOT BE APPROVED BECAUSE IT VIOLATES SECTION 1903(c) OF THE SOCIAL SECURITY ACT.

The statutes establishing the waiver provide only two vehicles for payment for services for individuals enrolled in the waiver; the Buckeye Account debit card, and once that is depleted, a managed care entity would provide payment for the benefits.

Regarding services covered under the waiver, Section 5166.401(A) of the Revised Code states in part:

> It shall cover physician, hospital inpatient, hospital outpatient, pregnancy-related, mental health, pharmaceutical, laboratory, and other health care services the Medicaid director determines necessary.

Section 5166.40(C) states:

> Except as provided in section 5166.406 of the Revised Code, a healthy Ohio program participant shall not receive medicaid services under the fee-for-service component of medicaid or participate in the care management system.

Section 5166.406 of the Revised Code states in part:

> If a healthy Ohio program participant exhausts the annual or lifetime payout limits specified in division (D) of section 5166.401 of the Revised Code, the participant shall be transferred to the fee-for-service component of medicaid or the care management system.

Ohio Medicaid offers its consumers four different options for getting health care services, Traditional Medicaid (Fee-For-Service), Medicaid Managed Care, Home and Community-Based Services, and Facility-Based Care. The effect of those statutes is to prohibit a Healthy Ohio enrollee from accessing both traditional Medicaid managed care and traditional fee-for-service, while still allowing the Healthy Ohio enrollee to access home and community based services and facility based care. That structure creates an access barrier to school based services.

Medicaid provides coverage of professional services in the Medicaid Schools Program (MSP). Those services include Occupational therapy services, Physical Therapy services, Speech-language pathology services, Audiology services, Nursing services, Mental health services. The MSP is part of Medicaid's fee-for-service system. See, Ohio Administrative Code 5160-35-04 and http://medicaid.ohio.gov/FOROHIOANS/AlreadyCovered/GettingCare.aspx. The MSP is not part of Medicaid Managed Care, Home and Community-Based Services, nor Facility-Based Care.

The MSP covers services authorized as part of an individual service plan authorized under the Individuals with Disabilities Education Act (IDEA) and includes individuals up to the age of 21. Some Healthy Ohio waiver enrollees would be entitled to receive IDEA covered services. The above statutes do not allow Healthy Ohio waiver enrollees to receive any IDEA authorized services under the Medicaid program. For that reason, the waiver cannot be approved by CMS.

Also, the approved state plan amendment for the MSP, section 4.19-B Items 6, 11, 13, 19, and 24, sets forth the exclusive reimbursement methodology for MSP services and includes a certified public expenditure component to that reimbursement. None of that is accommodated for by the statutes, and neither Healthy Ohio Waiver payment, nor a Buckeye Account debit card can be used to pay a public school district. For that reason, the waiver also cannot be approved by CMS.

Further, the secretary of HHS is not permitted to restrict payment for services furnished under the IDEA. Section 1903(c) of the Social Security Act states the following:

> Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

The waiver authority under Section 1115 of the Social Security Act does not permit restriction on payment for IDEA authorized services. Even if the MSP were able to be covered by Healthy Ohio plans or Buckeye cards, requiring 18, 19, and 21 year olds to use Buckeye accounts and requiring schools to contract with managed care plans is a "restriction" on payment for covered services. For that reason, the waiver cannot be approved by CMS.

Finally, the payment methodology for MSP providers cannot be altered without consulting multiple school districts that were parties to the matter of Kissel v. Ohio Department of Job and Family Services Franklin County CP. 05 CV 002796. That case involved litigation over the ending the Community Alternative Funding System (CAFS) program. That litigation ended with a settlement after extended negotiation between the state and the plaintiffs. Two public hearings and a public comment process are not appropriate vehicles for consulting with parties to a formal settlement.

III. THE WAIVER CANNOT BE APPROVED BECAUSE THE STATUTES ESTABLISHING THE WAIVER INTERFERE WITH ANOTHER FEDERAL BENEFIT.

The Healthy Ohio waiver cannot be approved because the statutes establishing the waiver bar access to Ryan White program benefits as provided for under the Ryan White Care Act. The Ryan White HIV/AIDS Program was established through the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 as a payer of last resort for HIV/AIDS patients seeking care, medication, and support services for their disease. It has been amended and reauthorized four times with its latest iteration the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009).

The Ryan White program is administered by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services. The program is comprised of four primary components, Parts A, B, C, and D, and functions through the distribution of grants to public or private awardees. Individuals who are eligible for Ryan White Services can receive coverage and/or services through one or more of the funded parts.

Part B grants to states include a base grant; the AIDS Drug Assistance Program (ADAP) award; and ADAP Supplemental Drug Treatment Program funds. ADAP funds are used in part to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. ADAP also pays enrollees' health care co-payments and health insurance premiums.

The Healthy Ohio statutes interfere with those benefits. Ohio Revised Code Section 5166.402 provides the following:

> (C) (1) Subject to divisions (A)(2), (D), and (F) of this section, a healthy Ohio program participant shall contribute each year to the participant's buckeye account the lesser of the following:
> (a) Two per cent of the participant's annual countable family income;
> (b) Ninety-nine dollars.
> (2) A participant's contributions to the participant's buckeye account may be made in monthly installments. A monthly installment payment shall be considered an initial contribution.
> (D) (1) Subject to division (D)(2) of this section, **the following may make contributions to a healthy Ohio program participant's buckeye account on the participant's behalf:**
> **(a) The participant's employer, but only up to fifty per cent of the contributions the participant is required to make;**
> **(b) A not-for-profit organization, but only up to seventy- five per cent of the contributions the participant is required to make;**

> **(c) The managed care organization that offers the health plan in which the participant enrolls under the healthy Ohio program, but both of the following apply to such contributions:**
> (i) They shall be used only to pay the costs for the participant to participate in a health-related incentive available under the health plan, such as completion of a risk assessment or participation in a smoking cessation program.
> (ii) They cannot reduce the amount the participant is required to contribute.
> (2) Contributions made on a participant's behalf under divisions (D)(1)(a) and (b) of this section shall be coordinated in a manner so that the participant makes at least twenty-five per cent of the contributions the participant is required to make. (Emphasis added).

Further, Revised Code Section 5166.403 provides that the account is to be used for the costs of health care services that are covered by the health plan and for copayments as required by Revised Code Section 5166.401(C).

These statutes do not allow contributions by another government program either to the Buckeye Account, or to pay copayments under Healthy Ohio. They unlawfully interfere with Ryan White benefits, as those are costs Ohioans with HIV are entitled to have paid by the Ryan White program. As such, the waiver cannot be approved.

Additionally, the provisions of state law are preempted by federal law. As explained above, the structure of the statutes and the waiver interfere with this important federal benefit.

Article VI, clause 2 of the United States Constitution states:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding. (Emphasis added)

Consistent with that command, the Supreme Court has long recognized that state laws that conflict with federal law are "without effect." Altria Group v. Good, 555 U.S. 70 (2008) citing Maryland v. Louisiana, 451 U. S. 725, 746 (1981). The proposed waiver cannot be approved because a non-negotiable element that is not severable is preempted by federal law.

IV. THE WAIVER CANNOT BE APPROVED BECAUSE IT VIOLATES THE NON-DISCRIMINATION PROVISIONS OF THE ACA AND WILL INCREASE THE RATE OF HIV TRANSMISSION IN OHIO.

In addition to flaws noted in these comments passim, the waiver violates the non-discrimination provisions of the ACA because it creates a barrier for HIV positive persons from accessing the care they need to stay engaged in care.

The Patient Protection and Affordable Care Act (ACA) prohibits health programs from discriminating against individuals on the basis of disability.[1] All health programs receiving federal funds must provide coverage of Essential Health Benefits (EHB), and a program does not provide coverage of EHB "if its benefit design, or the implementation of its benefit design, discriminates based on . . . present or predicted disability . . . or other health conditions."[2] ***Disability includes HIV, even when a person is in the asymptomatic phase of the illness.***[3]

> SEC. 1557. NONDISCRIMINATION.
> (a) IN GENERAL.—Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection. (Underscore added)

HHS has established that the Medicaid programs are health programs under this provision.[4]

The waiver design is inconsistent with the current standard of care for HIV as outlined by the Department of Health and Human Services (HHS), it is discriminatory against individuals living with HIV, and it violates an HIV positive persons entitlement under other federal laws established

[1] ACA § 1557, codified at 42 U.S.C. § 18116 (2012).
[2] ACA § 1311(c)(1)(A)(i); 45 CFR § 156.125, 45 CFR § 156.200(e), 45 CFR § 156.225, and 45 CFR § 147.104(e); *see also* ACA § 1557(a).
[3] *See, e.g., Bragdon v. Abbot*, 524 U.S. 624, 630–647 (1998) (ADA); *Doe v. County of Centre, Pa.*, 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); *Chalk v. United States Dist. Ct.*, 840 F.2d 701, 704–709 (9th Cir. 1988) (Rehabilitation Act).
[4] 80 FR 54171, at 54175.

for the express purpose of paying for an HIV positive persons insurance premiums, co-insurance, and copayments.

A combination of multiple antiretroviral medications is necessary to suppress the human immunodeficiency virus (HIV), and the most effective combination depends on factors unique to the individual. Left untreated, HIV can replicate by the billions every day, and as it does so, it mutates rapidly. Indeed, HIV has the highest mutation rate of any virus due to its uniquely error-prone process of transforming RNA into DNA. Because it mutates so rapidly, HIV quickly adapts and becomes immune to drugs when treated with only one type of drug at a time or when treatment is interrupted, even briefly.

The great breakthrough in HIV treatment came in the mid-90s when researchers discovered that effectively fighting the virus requires using multiple types of HIV drugs at the same time.[5] Combination treatments box the virus into a corner, decreasing the amount of the virus in the body to undetectable levels and allowing the immune system to function more normally.[6] Based on this insight, clinicians now combat the virus by prescribing a combination of the following types of antiretroviral drugs:[7] Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTIs), Protease Inhibitors (PIs), Non-nucleoside Reverse Transcriptase Inhibitor (NNRTIs), Entry Inhibitors (EIs), Fusion Inhibitors (FIs), and Integrase Inhibitors (IIs).

HHS guidelines describe the current "state of knowledge" and establish the medical standard of care for the "optimal use" of antiretroviral (ARV) agents for the treatment of HIV infection in adults and adolescents in the United States.[8] The guidelines are a living document that is updated as new treatments become available or new research studies are published. The guidelines include "recommended" regimens and "alternative" regimens[9] and are available online at: http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0.[10]

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[5] *History of HIV & AIDS in the U.S.*, AVERT, http://www.avert.org/history-hiv-aids-us.htm (last accessed October 17, 2014) ("[After being introduced], it soon became obvious that HAART was going to be revolutionary in HIV treatment."); *see also* HHS Guidelines at D-1 ("Achieving viral suppression requires the use of ARV [i.e., HAART] regimens with at least two, and preferably three, active drugs from two or more drug classes.").

[6] US DEP'T OF HEALTH AND HUMAN SERVS., GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS (last updated May 30, 2014), at E-1, *available at* http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (hereinafter "HHS Guidelines") ("The primary goal of antiretroviral therapy (ART) [i.e., HAART] is to prevent HIV-associated morbidity and mortality. This goal is best accomplished by using effective ART to maximally inhibit HIV replication so that plasma HIV RNA levels (viral load) remain below that detectable by commercially available assays. Durable viral suppression improves immune function and quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life.").

[7] U.S. Institute of Health, *Types of HIV Antiretroviral Drugs* (last updated Sept. 23, 2013); AIDS.gov, *Overview of HIV Treatments* (last revised Aug. 7, 2009).

[8] *See* HHS Guidelines at A-1 to A-2.

[9] For some individuals, the recommended regimens may not be effective. Therefore an alternative regimen may be the preferred regiment for some patients. HHS Guidelines at F-4.

[10] HHS Guidelines at F-4.

The multi-drug treatment, known as highly active antiretroviral therapy (HAART), has proven remarkably successful in improving immune function and overall health, delaying the onset of AIDS, and extending life expectancy to near-normal for people with HIV.[11] Proper use of medications has reduced deaths from 50,874 in 1995[12] to 13,712 in 2012.[13] The significant reduction in deaths is evidence that HIV medications save the lives of people with HIV. Effective treatment of people with HIV, also greatly benefits other members of the general public. By reducing the amount of virus in an individual with HIV's bodily fluids, HAART reduces the risk of transmission from infected individuals to their sexual partners by at least 96%[14] and perhaps 100%.[15] HAART also prevents women with HIV from transmitting the virus to their newborn children.[16] Therefore, HAART not only saves the lives of people with HIV, but protects the public health as well.[17]

To obtain all of these benefits, HAART should be initiated early and be taken daily without interruption.[18] Delaying treatment causes long-term damage to vital organs[19] and allows HIV to mutate extensively as it replicates throughout the body, risking the possibility that one of those

[11] *See* HHS Guidelines at D-1.

[12] *See* Denis H. Osmond, *Epidemiology of HIV in the United States*, at Table 3 (2003), *available at* http://hivinsite.ucsf.edu/InSite-KB-ref.jsp?page=kb-01-03&ref=kb-01-03-tb-03&no=3.

[13] *See* Centers for Disease Control and Prevention, *HIV in the United States: At a Glance* (last updated March 12, 2014), *available at* http://www.cdc.gov/hiv/statistics/basics/ataglance.html.

[14] A 2011 study, the HPTN 052 study, found that HAART reduced the risk of transmission by 96%. *See HPTN 052, Fact Sheet: Initiation of Antiretroviral Therapy (ART) Prevents the Sexual Transmission of HIV in Serodiscordant Couples*, HIV PREVENTION TRIALS NETWORK (July 2011), http://www.hptn.org/web%20documents/HPTN052/HPTN%20Factsheet_InitiationART4Prevention.pdf.

[15] A study, known as the PARTNER study, is currently ongoing in Europe. The study is funded by the National Institute for Health Research in the UK. As of March 2014, interim results show a transmission rate of zero, as no incident of transmission has been reported. The study is still ongoing and final results are not yet available. *See* Allison Rodger, et. al., *HIV transmission risk through condomless sex if the HIV positive partner is on suppressive ART: PARTNER study*, Presentation at CROI, Boston (Mar. 3-6, 2014), http://www.chip.dk/portals/0/files/CROI_2014_PARTNER_slides.pdf.
D. Donnell, et al., *Heterosexual HIV-1 Transmission After Initiation of Antiretroviral Therapy: A Prospective Cohort Analysis*, 375 Lancet 2092, 2095 (Jun. 2010) ("ART use by HIV-1 infected participants was associated with a 92% reduction in risk of transmission"); *see also* HHS Guidelines at A-1 ("[E]ffective treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners."); *id.* at E-1 ("[H]igh plasma HIV RNA is a major risk factor for HIV transmission and use of effective ART can reduce viremia and transmission of HIV to sexual partners.").

[16] HHS Guidelines at I-20 ("In pregnant women, an additional goal of therapy is prevention of perinatal transmission of HIV with a goal of maximal viral suppression to reduce the risk of transmission of HIV to the fetus and newborn. . . .").

[17] HHS Guidelines at E-4 ("The expanded use of ART to treat individuals with CD4 counts >500 cells/mm^3 has also demonstrated public health benefits . . . because the risk of HIV transmission is associated with level of viremia, from a public health standpoint, this reduction in community viral load can potentially reduce new HIV infections at the community level.").

[18] HHS Guidelines at i-ii ("Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression . . . ," including patients with a CD4 cell count >500/mm^3. "The recommendation for initiation of ART in patients with early infection . . . should be offered . . . .").

[19] HHS Guidelines at E-1 ("[Delaying treatment causes] cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancies.").

mutations will make the virus drug resistant.[20] Furthermore, **due to HIV's high mutation rate, even minor interruptions in the medication regimen can lead to drug resistance, which results in increased viral replication, fewer treatment options, higher transmission rates, reduced functioning of the immune system, higher opportunistic infections.**[21]

Any administrative process that interferes with that medication regimen is a violation of the ADA and will result in medication non-adherence, and subsequent HIV transmission. Medicaid does not provide EHB if its program design, or the implementation of its program design, discriminates based on an individual's age, expected length of life, *present or predicted disability*, degree of medical dependency, quality of life, *or other health conditions*.[22]

To not discriminate, Medicaid programs must allow clinicians to follow widely accepted care and treatment recommendations to provide the standard of care for patients with HIV in the U.S. At a minimum, all recommended drug regimens—including those described as the "alternative" regimens to first-line regimens—should be available and affordable to HIV patients without requiring the use of mail-order pharmacies, prior authorizations or other utilization management techniques that may delay access to treatment. For these reasons, the waiver cannot be approved by CMS.

[20] HHS Guidelines at H-4 ("Persistent HIV RNA levels >200 copies/mL often are associated with evidence of viral evolution and drug resistance mutation accumulation; this is particularly common when HIV RNA levels are >500 copies/mL.") (footnotes omitted); *id.* at D-1 ("Maximal and durable suppression of plasma viremia delays or prevents the selection of drug-resistance mutations, preserves CD4 T-cell numbers, and confers substantial clinical benefits, all of which are important treatment goals."); *id.* at C-10 ("Transmission of drug-resistant HIV strains is well documented and associated with suboptimal virologic response to initial antiretroviral therapy (ART).").

[21] HHS Guidelines at H-1 ("Discontinuing or briefly interruption therapy in a patient with viremia may lead to a rapid incase in HIV RNA and a decrease I nCD4 cell could and increase the risk of clinical progression"); *id.* at D-2 ("Suboptimal adherence may result in reduced treatment response"); *id.* at I-5 ("A large randomized controlled trial of patient with chronic HIV infection found that treatment interruption was harmful in terms of increased risk of AIDS and non-AIDS events").

[22] 45 C.F.R. § 156.125(a).

V. THE WAIVER CANNOT BE APPROVED BECAUSE IT PLACES HEALTHCARE PROVIDERS AND CHARITABLE ORGANIZATIONS AT RISK OF CIVIL MONETARY PENALTIES AND CRIMINAL PENALTIES.

Ohio Revised Code Section 5166.402 attempts to authorize employers and non-profit organizations to make contributions to an enrollee's buckeye account. Those funds would then be used by the individual to pay for services delivered under a federally funded health care program.

42 U.S.C. 1320a-7a states in part:

> (a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that—
> ***
> (5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a–7(h) of this title) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined);
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> ***
> shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service ***.
>
> ***
> In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1320a–7b (f)(1) of this title) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

Any non-for profit that makes a contribution to a Buckeye Account under Revised Code Section 5166.402 will be subject to civil monetary penalties.

Additionally, 42 U.S.C. 1320a-7b states in part:

> (b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

The statute, and proposed waiver encourages practices that may constitute serious violations of federal criminal law. Many hospitals, clinics, and other similar entities are non-profits. This statute would suggest that they would be permitted to make contributions to the individual's account. That simply is not correct. Further, there are no systems in place to track donations and then retroactively audit entities that may have a connection to the donor source to determine if there was some unlawful inducement or hidden unlawful referral. Until assurances that such a system is in place, the waiver cannot be approved. Finally, if a state agency administers an account and allowed the deposit of an illegal remuneration, then the state agency would be complicit in the illegal remuneration. For all of these reasons, the waiver cannot be approved by CMS.

VI. THE BUCKEYE ACCOUNT DOES NOT COMPLY WITH THE INTERNAL REVENUE CODE.

The deposits to the Buckeye Account fall within the Medicaid definition of unearned income under Ohio Adm. Code 5160:1-3-03.1 http://codes.ohio.gov/oac/5160:1-3-03.1v2 and therefore donations to such accounts by any person or entity other than the enrollee must be used to evaluate income eligibility for Medicaid. For certain individuals, deposits into the Buckeye Account could raise their income over the eligibility threshold for Medicaid. They will be disenrolled. For that reason, the waiver cannot be approved by CMS.

Further, the income is also taxable income under the Internal Revenue Code because the Buckeye Account does not qualify as a tax exempt Health Savings Account.

There are four federal requirements to be eligible for HSAs:

1. A person must be covered simultaneously by a qualified "high-deductible" health insurance policy (HDHP).
    a. For 2015, and 2016 participants in qualified HDHPs are required to pay the first $1,300 of their medical expenses ($2,600 for family coverage) before insurance benefits begin. (Conventional insurance plans, whose participants cannot contribute to HSAs, typically have had deductibles of about one-third to one-half these amounts; however many new health plans sold through ACA health exchanges have deductibles of $1,000 to $6,000 for 2014 through 2016.)
2. The HSA enrollee cannot be covered by any other health insurance plan, such as a spouse's plan.
3. The HSA enrollee must be under age 65.
4. The HSA enrollee cannot be claimed as a dependent on someone else's federal income tax return.

With that framework, the accounts under this waiver will not satisfy the first requirement because Medicaid is not a high deductible insurance policy. Some Medicaid enrollees have other insurance coverage so for them the second requirement would not be satisfied. There may be some parent caretaker relatives over the age of 65, and if so the third requirement would not be met for them. And finally there will be certain 18 year olds and certain students under the age of 24 that can be claimed as dependents.

Setting aside the dubious notion of allowing non-for-profit medical service providers to make payments to their customer's HSA, the HSA is in fact, not an HSA at all and has no tax exemption under the internal revenue code.

26 USC 63 states in part:

> (a)In general
> Except as provided in subsection (b), for purposes of this subtitle, the term "taxable income" means gross income minus the deductions allowed by this chapter (other than the standard deduction).

We were unable to find any deductions or exemptions for the Buckeye Account in the Internal Revenue Code in the area of "income". To comply with federal law, it would appear that the state or other entity managing the accounts would have to establish some manner of reporting for the IRS.

Additionally, we were also unable to find any tax exemption in the Ohio Revised Code for such an account.

Finally, if there were any doubt that this would be income, section 4.8 sets out the process for placing all funds into a bridge account for use after a person is disenrolled from Medicaid. We were unable to find any tax exemption for "bridge accounts" at the state or federal level. For all the above reasons, the waiver cannot be approved by CMS.

VII. THE PROPOSED WAIVER CANNOT BE APPROVED BECAUSE IT WOULD ELIMINATE A MANDATORY ENTITLEMENT.

The proposed waiver cannot be approved because it infringes on a constitutionally enforceable right for any individual described in section 1902(a)(10)(A)(i)(VIII) of the Social Security Act. The Medicaid expansion is optional for the state only in the context of federal enforcement under 42 U. S. C. §1396c. It is not optional for the state in the context of individual enrollee entitlement. The following explains why the mandatory categorical entitlement still exists and is still an enforceable right of individuals.

Federal-state cooperative programs that are enacted under the federal spending power, like Medicaid, fall within the Supremacy Clause and are the supreme law of the land. See Pennhurst State School and Hosp. v. Halderman, 451 U.S. 1 (1981).

Under the legal fiction developed in Ex Parte Young, 209 U.S. 123 (1908), a suit claiming violation of the constitution of a federal law by a state official is not barred by sovereign immunity. The requested injunctive relief can seek an order for the state official to comply with the law.

42 U.S.C. § 1983, creates a cause of action against any person who under color of state law deprives an individual of "any rights, privileges, or immunities secured by the Constitution and laws" of the United States.

Pursuant to § 1983, the Supreme Court has recognized a private right for suit and has outlined a framework to evaluate such claims. See Blessing v. Freestone, 520 U.S. 329 (1997).

Thus, the Medicaid Act's allowance for the Secretary of HHS to withhold funding to states in noncompliance with the Act under Section 1396c of the Act is not expressly the exclusive remedy under the Act.

In the matter of National Federation of Independent Business v. Sebelius,567 U.S. ___ (2012), 183 L. Ed. 2d 450, 132 S.Ct. 2566 the U.S. Supreme Court considered the limitations on the authority of Congress to enact laws under the Spending Clause of the United States Constitution. The Spending Clause grants Congress the power "to pay the Debts and provide for the . . . general Welfare of the United States." U. S. Const., Art. I, §8, cl. 1. The specific provision in question was the enactment of section 1902(a)(10)(A)(i)(VIII) which established the mandatory covered group commonly referred to as Medicaid expansion.

The public generally speaking consider the holding in National Federation to have made the "mandatory" group, an optional group that states could choose to not implement. That general view is incorrect.

The court analyzed the limits on Congress under South Dakota v. Dole, 483 U.S. 203 (1987). In South Dakota v. Dole, the court raised the idea that congressional action that rose to the level of

"coercion" could render an enactment unconstitutional. In the National Federation case, the Supreme Court concluded that if a state refused to implement Medicaid expansion, the threat of the Secretary withholding all Medicaid funds under 42 U. S. C. §1396c constituted coercion. On that basis the Court ruled that the Secretary was prohibited from applying §1396c to withdraw existing Medicaid funds for failure to comply with the requirements set out in the expansion. Finally, the Court noted that this fully remedied the constitutional violation and that all other provisions of the Medicaid act remained unaffected by the ruling. Having removed the provisions that raised the bar of "coercion", this leaves all other aspects of the Social Security Act intact.

We believe this leave individuals with a remaining private right of enforcement under 42 U.S.C. 1983 to maintain their full entitlement to coverage under section 1902(a)(10)(A)(i)(VIII) of the Social Security Act, because the financial inducement that amounted to coercion is no longer present, and because the Supreme Court holding expressly does not eliminate, or even address, individual entitlement to coverage. Stated simply, section 1902(a)(10)(A)(i)(VIII) is still a mandatory categorical covered group, that can only be enforced by the intended beneficiary of that provision.

CONCLUSION

Because the terms of the statutes authorizing the Healthy Ohio Waiver are non-negotiable, and because the statutes are patently in conflict with federal law, we urge the Center for Medicare and Medicaid Services to reject the waiver out right.

Respectfully,

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